K071734

510(k) Summary of Safety and Effectiveness Information

Regulatory Authority:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
Company:	**BioLase Technology, Inc. 4 Cromwell Irvine, CA 92618**
Contact:	**Ms. Ioana M. Rizoiu BioLase Technology, Inc. 4 Cromwell Irvine, CA 92618 Tel: (949) 226-8144 Fax: (949) 273-6680**
Trade Name:	***Waterlase® MD Derm***
Common Name:	**Er,Cr:YSGG laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX, MXF, DZI a Class II device**

Equivalent Devices:

Millenium™	Biolase Technology, Inc.
DermaLase™	Endo Technic Corp.
MCL 30 Dermablate	Asclepion Laser Technologies

Device Description:

The ***Waterlase®MD Derm*** medical laser system is a device used to perform a variety of soft tissue indications. Soft tissue procedures are performed using a different mode of operation where direct Er,Cr:YSGG laser energy is applied to incise, excise or ablate these tissues. For soft tissue procedures the water spray is applied for hydration, cooling or to keep tissues and the field of view clean.

A flexible fiber optic terminated into the handpiece delivers the ***Waterlase®MD Derm*** laser energy to the end fiber tip and target. A visible aiming light emitted from the handpiece's distal end pinpoints the area of treatment. Three fiber optic ports provide illumination from the handpiece to the tissue site in addition to the center beam emitting source. In soft tissue applications the power output, pulse duration, repetition rate (frequency) and air and water flow rates are adjustable to specific user requirements. The spot size and spot geometry can also be varied by changing tips which include different diameters and end configurations.

Indications for Use:

Use of the device is indicated for the incision, excision, ablation, vaporization and coagulation of dermatologic tissues including epidermal nevi, cheilitis, keloids, verrucae, skin tags, keratosis, scar revision, debulking of tumors, cysts, diagnostic biopsy and skin resurfacing.

Use of the device is further indicated for the incision, excision, vaporization and coagulation of soft tissue during general surgical applications where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

Cautions, Precautions and Contraindications:

All clinical procedures performed with ***Waterlase® MD Derm*** must be subject to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions, which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

The indications included herein are the same as indications that have been previously cleared by the FDA for other devices. Substantial equivalency for the ***Waterlase®MD Derm*** has been determined through comparison to previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Biolase Technology, Inc.
% Ms. Ioana Rizoiu
VP, Clinical Research and Development
4 Cromwell
Irvine, California 92618

Re: K071734
Trade/Device Name: Waterlase® MD Derm
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 29, 2007
Received: October 30, 2007

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K071734**

Device (Trade) Name: **Waterlase® MD Derm**

Indications for Use:

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Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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